REGULATIONS TO ASSURE PROTECTION OF PARTICIPANTS IN HUMAN RESEARCH

§ 22 VAC 30-40-10 Definitions.

The following words and terms, when used in this chapter, shall have the following meanings unless the context clearly indicates otherwise:

"Affiliated with the institution" means employed by the institution or a member of a household containing an employee of the institution.

"Board" means the Board of Rehabilitative Services for the Department of Rehabilitative Services.

"Commissioner" means the Commissioner of the Department of Rehabilitative Services.

"Department" means the Department of Rehabilitative Services.

"Human participant" means a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the individual, or (ii) identifiable private information. "Intervention" includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between investigator and participant. "Private information" includes information about the human participant's behavior that occurs when an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by the human participant which the participant can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the human participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

"Human research" means any systematic investigation which utilizes human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participant's needs.

"Institution" means the department, any center of independent living, sheltered workshop, Woodrow Wilson Rehabilitation Center, or any facility or program operated, funded, or licensed by the department.

"Independent living center" means a consumer controlled, community based, cross disability, nonresidential private nonprofit agency that:

1. is designed and operated within a local community by individuals with disabilities; and
2. provides an array of independent living services.

"Legally authorized representative" means the parent or parents having custody of a prospective participant, the legal guardian of a prospective participant, or any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant to such person's participation in the particular human research. For the purposes of this definition, any person authorized by law or regulation to consent on behalf of a prospective participant to his participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research and shall not be authorized to consent to nontherapeutic medical research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the participant.

"Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to general knowledge. Activities which meet this definition constitute research for purposes of these chapters, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some "demonstration" and "service" programs may include research activities.

"Research investigator" means the person, whether professional or student, who conducts the research.

"Sheltered workshop" means a facility based community rehabilitation program that provides directly or facilitates the provision of one or more of the following vocational rehabilitation services to individuals with disabilities to enable them to maximize their opportunities for employment, including career advancement:

1. medical, psychiatric, psychological, social, and vocational services that are provided under one management;
2. testing, fitting, or training in the use of prosthetic and orthotic devices;
3. recreational therapy;
4. physical and occupational therapy;
5. speech, language, and hearing therapy;
6. psychiatric, psychological, and social services, including positive behavior management;
7. assessment for determining eligibility and vocational rehabilitation needs;
8. rehabilitation technology;
9. job development, placement, and retention services;
10. evaluation or control of specific disabilities;

11. orientation and mobility services for individuals who are blind;
12. extended employment;
13. psycho-social rehabilitation services;
14. supported employment services and extended services;
15. services to family members when necessary to the vocational rehabilitation of the individual;
16. personal assistance services; or
17. services similar to the services described in 1-16.

"Voluntary informed consent" means the knowing, written consent of an individual, or the individual's legally authorized representative, so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion. With regard to the conduct of human research, the basic elements of information necessary to such consent shall include in writing:

1. A statement that the study involves research, and a reasonable and comprehensible explanation to the human participant of the procedures that the researcher will follow and their purposes, including identification of any procedures which are experimental; the expected duration of the human participant's participation; a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the individual will not be identified without his written permission;
2. A description of any attendant discomforts and risks to the human participant which may reasonably be expected and a statement that there may be other risks not yet identified;
3. A description of any benefits to the human participant or to others which may reasonably be expected;
4. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the human participant;
5. An offer to answer and answers to any inquiries by any individual concerning the procedure;

6. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the human participant is otherwise entitled, and the human participant may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;
7. An explanation of whom to contact for answers to pertinent questions about the research and human research participants' rights, and whom to contact in the event of a research-related injury;
8. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what it consists of or where further information may be obtained; and
9. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols.

§ 22 VAC 30-40-20 Authority.

These regulations are promulgated under the authority of §§ 51.5-5.1 and 51.5-14 of the Code of Virginia, to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of Title 32.1 of the Code of Virginia.

§ 22 VAC 30-40-30 Applicability.

These regulations shall apply to the Department of Rehabilitative Services, Woodrow Wilson Rehabilitation Center, any sheltered workshop or independent living center, and any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research which uses human participants.

§ 22 VAC 30-40-40 Policy.

A. No human research may be conducted without the voluntary informed consent of the participant or his legally authorized representative. The consent of the participant or his legally authorized representative to participate in the research must be documented in writing and supported by the signature of a witness not involved in the conduct of the research, except as provided for in section 22 VAC 30-40-100 F of this chapter. The research investigator shall sign and provide participants of a research study with a copy of the written voluntary informed consent statement as defined in 22 VAC 30-40-10 of this chapter. The investigator shall make arrangements for those who need special assistance in understanding the consequences of participating in the research.

B. Each human research study shall be approved by a committee composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities. An institution may establish its own research review committee, it may work with other institutions to establish a single committee, or it may use the department's established committee.

C. Nontherapeutic research using institutionalized participants is prohibited unless the research review committee determines that such nontherapeutic research will not present greater than minimal risk to the human participant.

D. The research investigator shall be required to notify all human participants in research of the risks caused by the research which are discovered after the research has concluded

§ 22 VAC 30-40-50 Certification process.

A. Institutions seeking to conduct or sponsor human research are required to submit statements to the research review committee assuring that all human research activities will be reviewed and approved by a research review committee. Institutions shall report annually to the commissioner giving assurance that a committee exists and is functioning. These reports should include a list of committee members, their qualifications for service on the committee, their institutional affiliation and a copy of the minutes of committee meetings.

B. Prior to the initiation of a human research project, institutions shall also send to the commissioner a description of the research project to be undertaken, which shall include a statement of the criteria for inclusion of a participant in the research project, a description of what will be done to the human participants, and a copy of the informed consent statement.

C. The commissioner may inspect the records of the research committee.

D. The chairman of the research committee shall report as soon as possible to the head of the institution and to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

§ 22 VAC 30-40-60 Composition of research review committees.

A. Each research committee shall have at least five members, appointed by the head of the institution or department, with varying backgrounds to provide complete and adequate review of activities commonly conducted by the institution. The committee shall be sufficiently qualified through the research experience, expertise, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its

advice and counsel in safeguarding the rights and welfare of participants in human research. In addition to possessing the professional competence necessary to review specific activities, the committee must be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews research that has an impact on an institutionalized or other vulnerable category of participants, including residents of mental health or mental retardation facilities, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these participants and who have appropriate experience to serve in that capacity.

B. No committee shall consist entirely of men or entirely of women, or entirely of members of one profession.

C. .Each committee shall include at least one of the following:

1. One member whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy);
2. One member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;
3. One consumer; and
4. One member whose primary concerns are in the scientific areas.

D. No member of a committee shall participate in the committee's initial or continuing review of any project in which the member is directly involved or for which he has administrative approval authority, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflict of interest with any study. The committee member shall be replaced in the case of a conflict of interest resulting in a decrease of the committee below five persons.

E. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals may not vote with the committee.

F. A quorum of the committee shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas.

G. The committee and the institution shall establish procedures and rules of operation necessary to fulfill the requirements of these regulations.

§ 22 VAC 30-40-70 Elements of each committee's review process.

A. No human research shall be conducted or authorized by the Department of Rehabilitative Services, any independent living center, sheltered workshop, or Woodrow Wilson Rehabilitation Center unless the committee has reviewed and approved the proposed human research project giving consideration to:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;
2. The degree of the risk, and, if the research is nontherapeutic, whether it presents greater than minimal risk;
3. Whether the rights and welfare of the participants are adequately protected;
4. Whether the risks to the participants are outweighed by the potential benefits to them;
5. Whether the voluntary informed consent is to be obtained by methods that adequately and appropriately fulfill the requirements of these regulations and whether the written consent form is

adequate and appropriate in both content and language for the particular research and for the particular participants of the research;

6. Whether the research investigators proposing to supervise or conduct the particular human research are appropriately competent and qualified;

7. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness;

8. Whether the research conforms with such other requirements as the board may establish; and

9. Whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants.

B. The committee shall review, at least annually, approved projects to ensure conformity with the approved proposal.

C. Research must be approved by the committee which has jurisdiction over the participant. When cooperating institutions conduct some or all of the research involving some or all of the participants, each cooperating institution is responsible for safeguarding the rights and welfare of human participants and for complying with this chapter, except that in complying with this chapter institutions may enter into joint review, rely upon the review of another qualified committee, or make similar arrangements aimed at avoiding duplication of effort. The committee chairperson may make such arrangements with the approval of a majority of the members present at a meeting of the committee.

D. The committee shall consider research proposals within 45 days after submission to the committee's chairman. In order for the research to be approved, it shall receive the approval of a majority of those members present at a meeting in which a quorum exists. A committee shall notify research investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure committee approval.

E. The committee shall develop a written description of the procedure to be followed by a human participant who has a complaint about a research project in which he is participating or has participated.

F. Any participant who has a complaint about a research project in which he is participating or has participated shall be referred to the chairperson of the committee who shall refer it to the committee to determine if there has been a violation of the protocol.

G. The committee shall require periodic reports. The frequency of such reports should reflect the nature and degree of risk of each research project.

§ 22 VAC 30-40-80 Kinds of research exempt from committee review.

Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from these regulations unless the research is covered by other sections of this chapter:

1. Research conducted in established or commonly accepted educational settings, involving commonly used educational practices, such as:

a. Research on regular and special education instructional strategies; or

b. Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.

2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is

recorded in such a manner that participants cannot be reasonably identified, directly or through identifiers linked to the participants.

3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; and either:

a. The participant's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of the participant's own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

a. The observations recorded about the individual, if they became known outside the research, could reasonably place the human participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if these sources are publicly available, or if the information taken from these

sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

§ 22 VAC 30-40-90 Expedited review procedures for certain kinds of research involving no more than minimal risk.

A. The committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if (i) another institution's or agency's human research review committee has reviewed and approved the project or (ii) the review involves only minor changes in previously approved research and the changes occur during the approved project period. Under an expedited review procedure, the committee chairperson and one or more experienced reviewers designated by the chairperson from among members of the committee may carry out the review . In reviewing the research, the reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with the nonexpedited procedure set forth in 22 VAC 30-40-70 of this chapter.

B. Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of research proposals which have been approved under the expedited review procedure.

C. Research activities involving no more than minimal risk and in which the only involvement of human participants will be in one or more of the categories referred to in 34 CFR 97.110.

§ 22 VAC 30-40-100 Informed consent.

A No human research may be conducted in the department, any independent living center, any sheltered workshop, or Woodrow Wilson Rehabilitation Center or approved by the research committee in the absence of voluntary informed, written consent. If the participant is competent at the time the consent is required, then the

consent must be subscribed to in writing by the participant and witnessed. If the participant is not competent at the time the consent is required, then the consent shall be subscribed to in writing by the participant's legally authorized representative and witnessed except as provided for in subsection F of this section. If the participant is a minor otherwise capable of rendering voluntary informed consent, the consent must be subscribed to in writing by both the minor and his legally authorized representative and witnessed. A research investigator shall seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the participant or the representative shall be in language understandable to the participant or the representative.

B. No individual shall participate in research unless this requirement is met for each individual. The giving of consent by a legally authorized representative shall be subject to the provisions of subsection C of this section. No voluntary informed consent shall include any language through which the participant waives or appears to waive any of his legal rights, including any release of any individual, institution or agency or any agents thereof from liability for negligence. Notwithstanding consent by a legally authorized representative, no person shall be forced to participate in any human research. Each human participant shall be given a copy of the signed consent form required by 22 VAC 30-40-40 A of this chapter, except as provided for in 22 VAC 30-40-100 F.

C. No legally authorized representative may consent to nontherapeutic research unless the committee determines that such nontherapeutic research will present no more than a minor increase over minimal risk to the participant. No nontherapeutic research shall be performed without the consent of the human participant

D. The committee may approve a consent procedure which does not include, or which alters some or all of the elements of informed consent set forth in 22 VAC 30-40-10 of this chapter. The committee may waive the requirements to obtain some or all informed consent provided the committee finds and documents that:

1. The research involves no more than minimal risk to the human participants;

2. The waiver or alteration will not adversely affect the rights and welfare of the human participants;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the human participants will be provided with additional pertinent information after participation.

E. Except as provided in subsection F of this section, the consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent required by 22 VAC 30-40-10 of this chapter. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or

2. A short form written consent document stating that the elements of informed consent required by 22 VAC 30-40-10 of this chapter have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the human participant or the representative, in addition to a copy of the short form.

F. The committee may waive the requirement for the research investigator to obtain a signed consent form for some or all participants if it finds that the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality and there is no greater than a minimal risk of physical or mental harm to the human participant. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes

will govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide participants with a written statement regarding the research.

§ 22 VAC 30-40-110 Committee records.

A. An institution, or when appropriate a committee, shall prepare and maintain adequate documentation of committee activities, including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants;
2. Minutes of committee meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution;
3. Records of continuing review activities;
4. Copies of all correspondence between the committee and the research investigators;
5. A list of all committee members;
6. Written procedures for the committee; and
7. Statements of significant new findings provided to participants.

B. The records required by this chapter shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

§ 22 VAC 30-40-120 Mandatory reporting.

Each research review committee shall submit to the governor, the General Assembly, and the commissioner or his designee at least annually a report on the human research projects reviewed and approved by the committee, including any significant deviations from the proposals as approved.

§ 22 VAC 30-40-130 Role of the department, commissioner, and the board.

A. The commissioner shall establish and maintain records of institutional assurances, annual reports, and summary descriptions of research projects to be reviewed by the board.

B. The commissioner shall review communications from committees reporting violations of research protocols which led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of the rights of human research participants. The board shall be kept informed of all reviews of violations of research protocol.

C. The commissioner shall arrange for the printing and dissemination of copies of these regulations.

§ 22 VAC 30-40-140 Applicability of state policies.

Nothing in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated by the board in response to §37.1-84.1 of the Code of Virginia.

§ 22 VAC 30-40-150 Applicability of federal policies.

Human research at institutions which is subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempt from this chapter. Such institutions shall notify the commissioner and the board annually of their compliance with the policies and regulations of federal agencies.

I certify that this regulation is full, true, and correctly dated

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H. Gray Broughton, CRC, CCM

Commissioner

Department of Rehabilitative Services

Date_____